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specified number of drug samples be delivered over a period of not more than 6 months, with the actual delivery dates for parts of the order to be set by subsequent oral communication or electronic transmission, is not considered to be a standing request.

§ 203.36 Fulfillment houses, shipping and mailing services, comarketing agreements, and third-party recordkeeping.

(a) *Responsibility for creating and maintaining forms, reports, and records.* Any manufacturer or authorized distributor of record that uses a fulfillment house, shipping or mailing service, or other third party, or engages in a comarketing agreement with another manufacturer or distributor to distribute drug samples or to meet any of the requirements of PDMA, PDA, or this part, remains responsible for creating and maintaining all requests, receipts, forms, reports, and records required under PDMA, PDA, and this part.

(b) *Responsibility for producing requested forms, reports, or records.* A manufacturer or authorized distributor of record that contracts with a third party to maintain some or all of its records shall produce requested forms, reports, records, or other required documents within 2 business days of a request by an authorized representative of FDA or another Federal, State, or local regulatory or law enforcement official.

§ 203.37 Investigation and notification requirements.

(a) *Investigation of falsification of drug sample records.* A manufacturer or authorized distributor of record that has reason to believe that any person has falsified drug sample requests, receipts, or records, or is diverting drug samples, shall:

(1) Notify FDA, by telephone or in writing, within 5 working days;

(2) Immediately initiate an investigation; and

(3) Provide FDA with a complete written report, including the reason for and the results of the investigation, not later than 30 days after the date of the initial notification in paragraph (a)(1) of this section.

(b) *Significant loss or known theft of drug samples.* A manufacturer or authorized distributor of record that distributes drug samples or a charitable institution that receives donated drug samples from a licensed practitioner shall:

(1) Notify FDA, by telephone or in writing, within 5 working days of becoming aware of a significant loss or known theft;

(2) Immediately initiate an investigation into the significant loss or known theft; and

(3) Provide FDA with a complete written report, including the reason for and the results of the investigation, not later than 30 days after the date of the initial notification in paragraph (b)(1) of this section.

(c) *Conviction of a representative.* (1) A manufacturer or authorized distributor of record that distributes drug samples shall notify FDA, by telephone or in writing, within 30 days of becoming aware of the conviction of one or more of its representatives for a violation of section 503(c)(1) of the act or any State law involving the sale, purchase, or trade of a drug sample or the offer to sell, purchase, or trade a drug sample.

(2) A manufacturer or authorized distributor of record shall provide FDA with a complete written report not later than 30 days after the date of the initial notification.

(d) *Selection of individual responsible for drug sample information.* A manufacturer or authorized distributor of record that distributes drug samples shall inform FDA in writing within 30 days of selecting the individual responsible for responding to a request for information about drug samples of that individual's name, business address, and telephone number.

(e) *Whom to notify at FDA.* Notifications and reports concerning prescription human drugs and biological products regulated by the Center for Drug Evaluation and Research shall be made to the Division of Compliance Risk Management and Surveillance (HFD–330), Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers

Lane, Rockville, MD 20857. Notifications and reports concerning prescription human biological products regulated by the Center for Biologics Evaluation and Research shall be made to the Division of Inspections and Surveillance (HFM–650), Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852.

[64 FR 67756, Dec. 3, 1999, as amended at 69 FR 48775, Aug. 11, 2004; 70 FR 14981, Mar. 24, 2005]

§ 203.38 Sample lot or control numbers; labeling of sample units.

(a) *Lot or control number required on drug sample labeling and sample unit label.* The manufacturer or authorized distributor of record of a drug sample shall include on the label of the sample unit and on the outside container or packaging of the sample unit, if any, an identifying lot or control number that will permit the tracking of the distribution of each drug sample unit.

(b) *Records containing lot or control numbers required for all drug samples distributed.* A manufacturer or authorized distributor of record shall maintain for all samples distributed records of drug sample distribution containing lot or control numbers that are sufficient to permit the tracking of sample units to the point of the licensed practitioner.

(c) *Labels of sample units.* Each sample unit shall bear a label that clearly denotes its status as a drug sample, e.g., ''sample,'' ''not for sale,'' ''professional courtesy package.''

(1) A drug that is labeled as a drug sample is deemed to be a drug sample within the meaning of the act.

(2) A drug product dosage unit that bears an imprint identifying the dosage form as a drug sample is deemed to be a drug sample within the meaning of the act.

(3) Notwithstanding paragraphs (c)(1) and (c)(2) of this section, any article that is a drug sample as defined in section 503(c)(1) of the act and § 203.3(i) that fails to bear the label required in this paragraph (c) is a drug sample.

§ 203.39 Donation of drug samples to charitable institutions.

A charitable institution may receive a drug sample donated by a licensed practitioner or another charitable institution for dispensing to a patient of the charitable institution, or donate a drug sample to another charitable institution for dispensing to its patients, provided that the following requirements are met:

(a) A drug sample donated by a licensed practitioner or donating charitable institution shall be received by a charitable institution in its original, unopened packaging with its labeling intact.

(b) Delivery of a donated drug sample to a recipient charitable institution shall be completed by mail or common carrier, collection by an authorized agent or employee of the recipient charitable institution, or personal delivery by a licensed practitioner or an agent or employee of the donating charitable institution. Donated drug samples shall be placed by the donor in a sealed carton for delivery to or collection by the recipient charitable institution.

(c) A donated drug sample shall not be dispensed to a patient or be distributed to another charitable institution until it has been examined by a licensed practitioner or registered pharmacist at the recipient charitable institution to confirm that the donation record accurately describes the drug sample delivered and that no drug sample is adulterated or misbranded for any reason, including, but not limited to, the following:

(1) The drug sample is out of date;

(2) The labeling has become mutilated, obscured, or detached from the drug sample packaging;

(3) The drug sample shows evidence of having been stored or shipped under conditions that might adversely affect its stability, integrity, or effectiveness;

(4) The drug sample is for a prescription drug product that has been recalled or is no longer marketed; or

(5) The drug sample is otherwise possibly contaminated, deteriorated, or adulterated.

(d) The recipient charitable institution shall dispose of any drug sample found to be unsuitable by destroying it